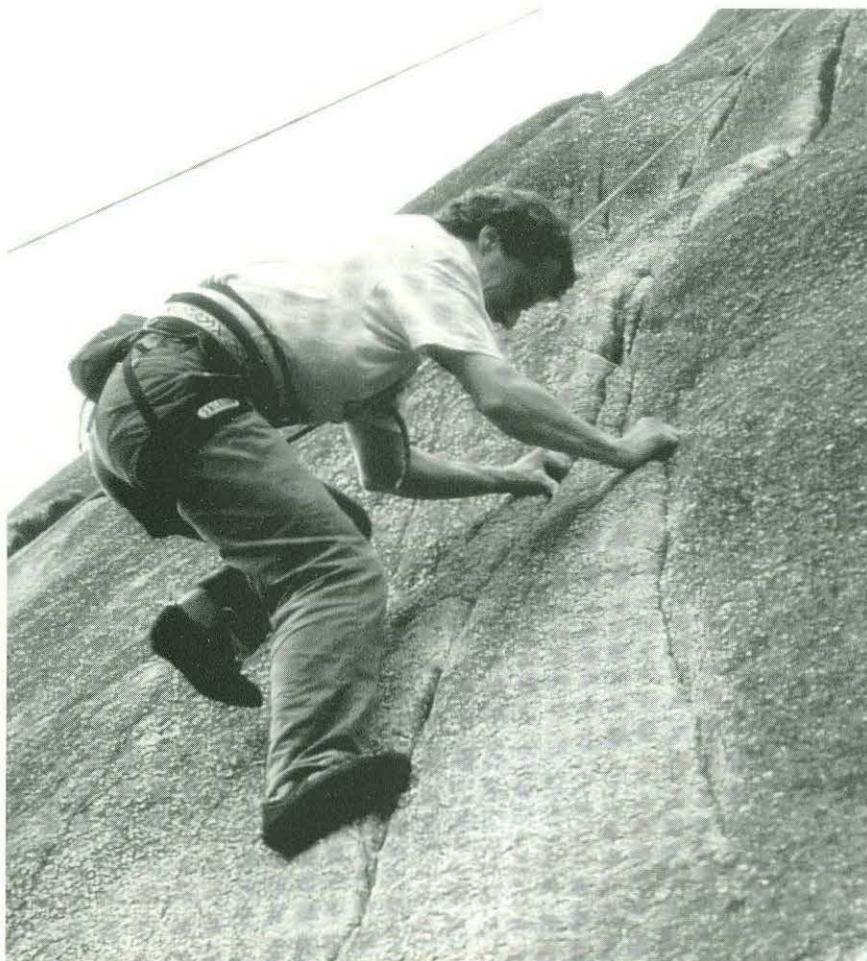

The Write Stuff

The Journal of the European Medical Writers Association

Challenging Situations



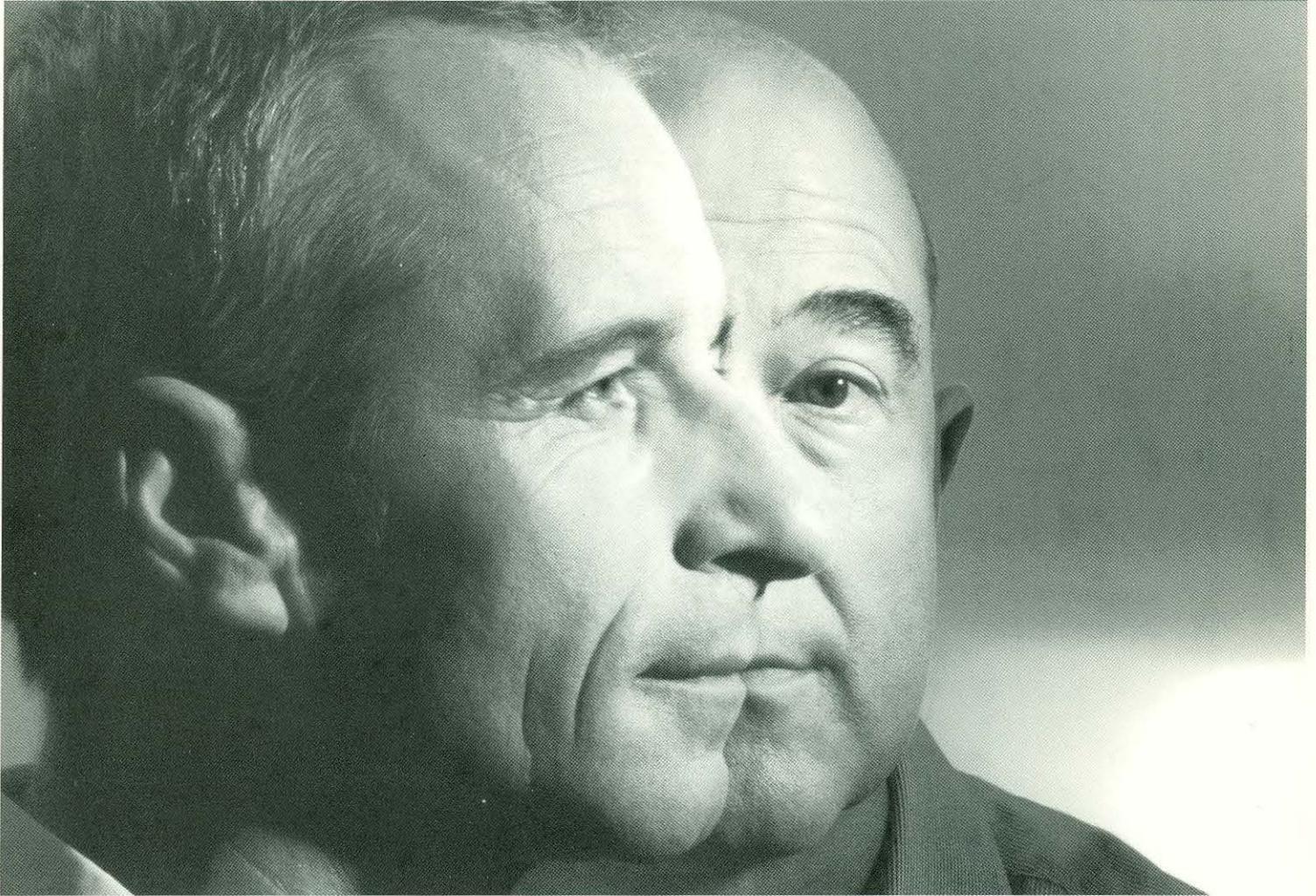
EMWA European
Medical Writers
Association

Vol. 10, No. 4, 2001

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Challenging Situations Vol. 10, No. 4, 2001

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How about having a baby as a really excellent reason for quitting the corporate grind, becoming a freelancer, and working at home? On the other hand, this is a decision made due to external (or internal, depending on your point of view) reasons and poses a series of possibly daunting questions: How do I start? How do I find customers? How do I find the time? Find out about the experiences of one EMWA member who tried it and lived to tell the tale. [INT]	
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[INT] - this symbol indicates that the article also has been or will be published at the EMWA internet site:
<http://www.emwa.org>

The cover image was taken from a photograph by Finola Kirstein taken in Squamash, British Columbia, Canada.

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued quarterly and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

Articles or ideas should be submitted to the Editor-in-Chief (see back cover for address) or another member of the Editorial Board.

Subscriptions

Subscriptions are included in EMWA membership fees. Non-members can subscribe at an annual rate of:

- £20 within Europe
- £30 outside Europe

Instructions for Contributors

- **The Write Stuff** typically publishes articles of 500 - 1500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted electronically on computer diskette or by email as an MS Word file using Arial font (or equivalent), 11 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style).

Back Issues

Subject to availability, previous issues of **The Write Stuff** can be obtained for the cost of mailing by contacting the EMWA secretariat.

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From the Editor's Desk: Is the Pen Mightier than the Bomb?

by Barry Drees

"The best thing for being sad,' Merlin advised the fatherless young Arthur, 'is to learn something. That is the only thing that never fails. You may grow old and trembling . . . you may miss your only love, you may see the world about devastated by evil lunatics, or know your honour trampled in the sewers of baser minds. There is only one thing for it then—to learn. Learn why the world wags and what wags it. That is the only thing which the mind can never exhaust, never alienate, never be tortured by, never fear or distrust, and never dream of regretting. Learning is the thing . . .'"

TH White, The Once and Future King

I think that everyone must have been affected in some way by the terrible terrorist attack in the USA in September with the horrific loss of life of people of all ages, races, religions and nationalities. And now the world is bracing for the challenges of an uncertain aftermath. News magazines have discussed these events from every imaginable angle and in unremitting detail, but it seems as if **every** magazine or journal I have looked into seems to have at least some kind of comment. But TWS? What possible contribution can a medical writing journal make to this subject. Well, at the risk of sounding trite, let me make the humble suggestion that scientific writers have an important role to play in combating the ignorance that is the fertile breeding ground for the fanaticism that leads to terrorist violence.

After the horror of this event, it seems as if the entire civilised world has begun to discuss what can be done about terrorism. The military people are telling us that this will be a "new kind of war" and that the world should prepare for a struggle which could last a long time. Those of a more political ilk, argue that we will never rid the world of terrorism without addressing the political problems that lead to the anger and frustration that inspires people to sacrifice their lives for a belief. However, I believe that history shows us that neither of these approaches will truly lead to the elimination of this threat. Rather, I believe that what is needed, and it is unfortunately a very long-term solution, is education, and in particular, science education.

Let's face it, terrorism comes from irrational passions and irrational passions arise most easily in an atmosphere of ignorance. By focusing on Islamic terrorists, we blind ourselves to the universals shared by all terrorists. If we consider the anti-government terrorists in the USA who executed the bombing attack in Oklahoma City a few years ago, it becomes evident that terrorism can arise anywhere where there is deep and fundamental ignorance about the world and how it works. There does seem to be a relationship between terrorism and ignorance, particularly scientific ignorance. A scientifically literate populace seems to be critical as schooling alone is apparently not enough (the word "Taliban" is variously translated as "Students" or "Seekers of truth" and refers to the fact that the founders of the Taliban were theology students).

From the Editor's Desk

And who are some of the most important people for increasing scientific literacy in the world? You guessed it, scientific communicators, and that includes medical writers. As I have discussed elsewhere [1], although science teachers obviously have an important role to play in fighting scientific illiteracy, nothing will really be achieved without doing something to maintain scientific knowledge and interest after school and encourage scientific literacy in the population as a whole, rather than just in school children.

Now I'm not so naïve as to think that medical writers working within the pharmaceutical industry are going to do anything about fanatical terrorist violence tomorrow. But as even George W Bush acknowledges, this is not going to be a short struggle, and in the long term, one of our most promising strategies has to be the fighting of scientific ignorance. It is in that struggle that we have an important role to play, wherever and however we contribute. So next time you find yourself hacking away through the thicket of an impenetrable study plan text, take a moment to reflect on the importance of scientific communication to the world and your part, however small, in furthering that goal.

Certainly this is a time filled with challenging situations. In this issue we present two very challenging professional situations experienced recently by EMWA members and how they dealt with them. Even if some of us will never be working mothers or (hopefully) experience workplace bullying, it is always helpful to know how others have met such challenges and overcome them. Perhaps, they can even inspire us to rise to meet our own challenges, whatever they are, with hope and confidence. It might help to remember: "*The Chinese ideograms for the words 'crisis' and 'opportunity' are the same*" [2].

References:

1. Drees, B. Can medical writing save western civilization? Write Now 1999: p4.
2. Rosenberg D, Gegax TT, Lipper T. War on terror. Newsweek 29 Oct 2001: p27.

Barry Drees
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The editorial board of TWS and the members of the Executive Committee would like to extend their condolences to any EMWA, AMWA, AuMWA members, or indeed anyone involved in scientific communication anywhere in the world who have suffered personal losses from the terrorist attacks and subsequent related violence all over the world.



Message from the President . . .

by Julia Forjanic Klapproth

Challenges are a part of life. Forget adventure games, there is nothing more challenging than setting a real-life goal and then trying to achieve it. There are hurdles and pitfalls, unexpected bends in the path, revelations and moments of elation when we overcome tricky situations and realise we've moved a step closer to the goal.

As in any profession, medical writing has its own collection of challenges that we all need to face. Sometimes it is good to know that we aren't alone in our struggles, and sometimes it can be useful, even inspiring, to see that peers and colleagues are experiencing similar situations and how they deal with them. This issue of TWS brings you two articles from medical writers who were faced with challenges in their careers. Bryanie Shackell, in "Dealing with Workplace Bullying", tells us how she was chased from her company and how she stood up for her rights. In "Medical Writing at Home", Alison McIntosh gives us insight into the challenges she encountered when she shifted to a home office after having a child. Standing up for your rights in the corporate world and adjusting to a new environment (especially working at home after having worked in a busy office) is something we all experience in some form or another in our professional sphere. These two articles give us an example of how two of our peers approached these challenges and worked to overcome them.

Key to fighting those battles effectively is being informed and having the right tools and battle companions

Another new challenge that will affect the professional lives of many medical writers is the advent of the Common Technical Document (CTD).

The recent EMWA seminar on the CTD, held on November 8, 2001 in Brighton, gave us an opportunity to face the challenge and begin the task of surmounting it. The event was very informative and the discussion session in the afternoon gave people plenty of time to voice their concerns and clarify the implications of actually applying the new format at a global level. It was a day of communication that provided answers to many questions. By the end, I think all the participants had benefited from the experience, coming away armed with new perspectives and insight into putting the CTD into effect and the role of the medical writer in doing so.

In my opinion, the rewards of a career lie to a large extent in battling with the challenges one faces, for it is there that we find our sense of achievement and fulfilment when they are finally overcome. However, the key to fighting those battles effectively is being informed and having the right tools and battle companions. To this end, I hope that EMWA will continue to be a point of reference in the medical writing community, where we can come together to share experiences and gather support and inspiration to tackle the challenges life throws our way.

Message from the President

Now I have a challenge for you. In this issue we are setting in motion an official process for nominating members to be elected to the EMWA Executive Committee. I am calling on you to think about whether or not you feel you could contribute to EMWA by standing for election to one of the offices that is open. Read the announcement, check out the descriptions of these positions that have been posted on the website, and give the idea some thought. Here is your chance to get involved in what we are and what we do.

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Call for Nominations

The following positions will be open for re-election at the next Annual General Meeting, to be held in May, 2002 at the annual conference in Prague.

- **Vice-President**
- **Public Relations Officer**

To be eligible for nomination, an individual must be a member of EMWA and have attended at least one of the last three EMWA annual conferences. In addition, for the post of the Vice President, the individual must have served in a post of the EMWA Executive Committee or Educational Committee for at least one year.

Any member can nominate themselves (if eligible) or another eligible member for the vacant positions. Nominations should be submitted in writing to the EMWA Head Office at the address on the back page of this journal, or to any of the members of the Executive Committee. Nominations must be received **on or before 26 February, 2002.**

Remember, EMWA is an organisation of the members for the members. To make the voting meaningful for all the members, nominees will be requested to provide a brief justification of why they want to run for the post, and why they feel fit for that office. All nominees will be announced in the next (pre-conference) issue of TWS, together with their justifications.

Descriptions of the responsibilities for all posts on the executive committee can be found on the website at www.emwa.org. If you would like to get more involved in EMWA, or think you know someone who would be a good representative on the executive committee, then let us know.



Medical Writing at Home

by Alison McIntosh

As with most people who work for a pharmaceutical company in these days of mergers and acquisitions, I was used to hearing management extol enthusiastically "Embrace change!" More often than not the usual retort was "We can embrace change but we don't have to give it a big kiss!" Well, just over a year ago, I had to embrace change and give it more than one big kiss, and a few hugs too. The change in this case came in the shape of Sarah and weighed in at 7lb 3oz.

Prior to Sarah's arrival, I had every intention of returning to work full-time and continuing my life as it was, with the baby just slotting in. How wrong could I be? My maternity leave ended in May 2000 and at that point I had to make a choice. I wanted to balance family and work commitments more evenly and chose not to return to the safe environment of a full-time medical writing position in a blue-chip company. I found this a hard decision to make, principally because I had spent years in academia jumping from one temporary contract to another and finally left to join the pharmaceutical industry as the permanent and safe option.

I knew I wanted to continue my medical writing and decided to begin life as a freelancer. This, I reasoned, would allow me to have flexible working arrangements, whilst still maintaining my own professional development at an adaptable pace. Freelance medical writing also meets a major requirement of the modern workplace - a portable skill. In theory, if you have the right technology, writing can take place in almost any locale. Hence, future changes in location should not matter to clients.

Next problem, how do I become a freelance medical writer? I needed information not required as a full-time employee. Should I be self-employed or a Limited Company? Self-employed status, how does the tax-man know? Talking of tax-man, how do you pay tax and national insurance contributions? Accounts, do I need an accountant? How do I decide when I am self-employed, do I have to have earned money first? So where can you turn to for help in the UK?

I had every intention of returning to work full-time and continuing my life as was, with the baby just slotting in. How wrong could I be?

I turned to Business Link, a UK national organisation with local centres dedicated to helping people set up a business and providing them with ongoing support. My local office in Leicester was a treasure trove of help and guidance, proving to be an inexpensive and useful way of finding important information very quickly. Within the first week of contacting them, I had a one-to-one session with an experienced small business consultant and my list of questions kept him very busy indeed. They ran a

Medical Writing at Home

two-day start-up course covering all the basic information needed to begin your business, and by attending, I received two years' free banking. I also enrolled on their one-day accounting course which I found invaluable. I am currently waiting to attend a one-day course aimed at improving business websites.

After completing my first year, do I think freelancing is an easy option? I don't think so. As a freelancer working from home, you have to be disciplined and also not be afraid of working alone. When you feel like a chat to break up a particularly long piece of work, there are no colleagues to wander along to and pass the time of day with. You have sole responsibility for attracting business to your company, therefore you can't take it too personally when you send out your CV to a potential client and receive the umpteenth response that they have no work at the moment but will keep your details on file. As a freelancer, you have to believe that they mean it. You have to maintain your own enthusiasm and drive, deriving pleasure from completing a piece of work to a

You have to maintain your own enthusiasm and drive, deriving pleasure from completing a piece of work to a high standard and on time.

high standard and on time. With no one else to rely on, you must be willing to tackle new skills. I personally got a lot of fulfilment out of designing and building AAG Medical Writing's website and publishing it on the internet.

On several occasions during this last year, I have discovered that medical writing is not widely recognised as a profession. Business

Link runs a mentoring scheme designed to put a new business in touch with experienced people in similar occupations. No medical writer had previously been enrolled, hence no mentor existed for my new business venture. I registered as unemployed until I obtained my first commission and discovered in the process that I did not exist as an employment category. After asking whether I was a journalist/secretary/scientist, the pull-down menu was left blank! Is this something EMWA should take note of? Perhaps even offering mentoring services from within the association through a freelance network?

Overall, how has the first year been? Very different from previous employment years. In addition to being the Medical Writer for AAG Medical Writing I have had to learn to be the Business Development Officer, the Accountant, the Budget Manager, the IT and Website Developer, Uncle Tom Cobley and all. I have successfully obtained several medical writing commissions and in July of this year my accountant said he was impressed by my accounts - praise indeed! I'd be happy to hear from any readers on any of the issues or topics raised in this article.

Useful Addresses:

England: 08456 045678	www.businessadviceonline.org
Wales: 08457 969798	www.businessconnect.org.uk
Scotland: 0845 6096611	www.sbgateway.com
No. Ireland: 028 90 491031	www.ledu-ni.gov.uk

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Dealing with Workplace Bullying

by **Bryanie Shackell**

Last year I returned to a profession that I had found myself unintentionally diverted from almost twenty years ago. I had had every intention of continuing my nursing career when I left the Queen Alexandra's Royal Naval Nursing Service (QARNNS), but instead I found myself accepting the opportunity of a university education I had never thought possible.

After six very enjoyable, and surprisingly successful, years at university, I emerged from academia with my PhD, and a short while later fell into pharmaceutical research in a clinical trials unit. The size of the unit demanded multi-tasking and at various times during my ten years of employment I was responsible for the laboratory, data management, quality assurance, medical writing and clinical nurse training. Having three children during this time only affected the amount of time I spent at work. Changing to three long days a week was carefully orchestrated by the employment of excellent nannies, so that my fear of having to take time off work if the children were ill was confined to only real emergencies. The initial reaction to my first impending motherhood had been negative and unpleasant, and had left me feeling paranoid and unsure about how long I would be in my job. However, as a wise man once said, "Just because you're paranoid, doesn't mean they're not out to get you".

Despite the commitment and effort put into my work over the next six years, during my maternity leave in 1999, I applied to undertake the government-funded "Return to Nursing" course. I had not been gripped by postnatal psychosis, nor was I fulfilling an altruistic dream to nurse the sick and injured of society, and I had certainly not succumbed to the government's half-hearted attempts to seduce nurses back into the profession. Similarly I had no particular desire to replace my relatively desk-bound occupation with one that carries a high risk of varicose veins and back problems.

My experiences at work since my first pregnancy had left me feeling increasingly fearful about my future in the organisation. Having already survived one very personally directed threat of job loss, loss of status and loss of income, and having been subjected to discrimination, isolation, exclusion and obstruction, I felt less than comfortable about what might befall me once I returned to work. Not wanting to be caught "up the creek without a paddle" with three small children, I was taking a positive step towards protecting myself from unemployment.

The most rewarding part of what was initially a very negative experience is that I have retained my self-respect and professional integrity, and have refused to be beaten

Workplace Bullying

The local opportunities for similarly paid work have always been few and far between, and I was concerned as to how I would continue to earn sufficient income to maintain my family's lifestyle if I was forced to leave. Despite having established myself as a freelance medical writer, I knew that this could be a "feast or famine" lifestyle and should not be depended upon for a reliable income. Updating my nursing skills gave me the security of knowing that I could return to my former profession, either to earn extra cash or to avoid the extreme financial hardship of unemployment.

Although the course was free to participants, the time commitment was heavy, and whilst undertaking the eighty hours of unpaid experience on the wards, I incurred hefty childcare costs and an additional quota of fatigue. I returned to work at the clinical trials unit summoning hope and enthusiasm for a fresh start. My colleagues welcomed me with open arms and their friendship and support was encouraging.

When I set to the unenviable task of doing my job as Quality Assurance manager, it became clear that nothing had changed, and I still did not have support from some of the higher echelons. My ideas, initiatives and contributions to meetings were still ignored and frequently omitted from the minutes. My authority and seniority in the company were openly undermined and belittled, and I was discriminated against for

One of my junior assistants was offered a perk offered to senior and less senior staff than me, and told to keep it a secret, as I was not to be included.

being part-time. Attempts were made to destroy the good working relationship I had with my staff by a "divide and conquer" technique.

My response was to voice my grievance at the underhand methods employed and to continue to do my job as best I could given the circumstances. I tried to initiate systems to promote quality and safety, being sensitive to

the staff's needs for confidentiality regarding their concerns. The opposition and obstruction that followed were predictable, but I was completely unprepared for the public humiliation and aggression inflicted upon me at the next staff meeting. My efforts to improve quality and safety were undermined and ridiculed and my manager personally subjected me to an aggressive verbal attack. A colleague subsequently described the atmosphere after the meeting as "one of shock, almost everyone voiced the opinion that Bryanie had been very badly treated".

After the meeting, there was no doubt as to how these individuals felt about me. After six years, it was out in the open. I felt that I would no longer have the confidence and trust of the staff, and it would be impossible to expect co-operation and respect when there was so obviously a lack of both from above. I could see no option other than to resign.

In the immediate aftermath, I felt a mixture of relief and anger. Close friends suggested that I should make a claim of constructive dismissal, but at the time, I feared any further opportunity for humiliation. When I began to surface from my muddy puddle of emotions and the many post-mortems of the event, I tried to organise my thoughts and turned to my solicitor for advice. I remembered a previous employee who had left it too late to take legal action, and thought that I should at least seek advice early, although I did not at that time feel ready to do so. The solicitor agreed that I had been badly treated, but stressed how difficult it is to prove constructive dismissal.

Throughout the years I had been advised to document all the bad events, grievances and other relevant correspondence. Having no option other than to represent myself at the tribunal, I struggled for days to assemble the documents and details into a statement, omitting the seemingly "more trivial" events despite their impact on me at the time. Then one night I stumbled onto the "Bully OnLine" website [1]. I could not believe that my experiences and the perpetrators of my grievances were described so accurately. It was only then that I recognised myself as a victim of workplace bullying and identified each of my experiences as significant pieces of the whole jigsaw puzzle. I put hours of work into my comprehensive and undeniable record of victimisation and, some weeks and twenty-three pages later, I was satisfied with the final document and the money I had saved by not having my solicitor do it!

I was further blessed with three witnesses, without whom it would have been difficult to defend my case. I shall always be grateful to them for their encouragement and support and, when I needed it most, their sense of humour.

In the eight-month period leading up to the tribunal, there was a series of devious attempts to force my withdrawal. The tribunal date was delayed several times, I was told that my claim was "vexatious, frivolous and unreasonable" and that they would apply for costs against me if I proceeded to tribunal. However I might also have been charged with their legal costs if I had withdrawn my claim. The delays and threats were no doubt intended to push up my own costs and wear me down so that I would buckle and bow out.

In the eight-month period leading up to the tribunal, there was a series of devious attempts to force my withdrawal

Contrary to this, the delays only lengthened the interval since I had left and this had a significantly positive effect on my mood. One of my greatest concerns had been seeing my adversaries at the tribunal, but the sudden realisation that they no longer had any hold over me encouraged me considerably. The continuation of their tactics of intimidation and the sheer dishonesty of some of their statements made me more determined to expose them and less likely to surrender. When I had worked for them, my hands had been tied; once I was free of them, I intended to redress the balance and show that I was not prepared to live my life like a beaten puppy.

In true QA style, I carefully audited each document that was sent to me and highlighted all the inconsistencies and inaccuracies that littered the text. I was heartened by my ability to laugh at what they had concocted in their defence. Even when they had seen my statements and the "bundle of documents" providing the evidence in support of my claim, they persisted in contradicting it, even stating that they had paid for the Return to Nursing course. I found their witness statements weak and unconvincing.

On a foul wet day in December, we met at the tribunal office and they came out in force to play their next move: further delays. Having agreed to photocopy my statements as part of the trial bundle, their solicitors had not done so. Furthermore, they immediately requested that the tribunal be rescheduled yet again, for a two-day hearing. A date was set for February, but two days later a settlement offer appeared. Although it had increased by a factor of ten from the last offer, it was similarly unacceptable and I rejected it. We survived Christmas, still intent on facing them at tribunal if necessary,

Workplace Bullying

but in February an acceptable out-of-court settlement was agreed. That was ten months ago. The memory of the tribunal proceedings is fading, but the feelings relating to what went before will take a little more time.

On a positive note, although it has been hard returning to nursing after twenty years absence, my experiences on the wards have boosted my conviction that I had to resign when I did, and have reaffirmed my commitment to achieving high standards in clinical research. Nursing has brought me back into touch with life, death and the very real suffering of patients and their families, a vision of whom should be at the back of every clinical professional's mind. The distance between early clinical trials and patients does not represent a "comfort zone"; clinical trial data must be collected to the highest possible standard from day one if drugs are to be prescribed with confidence.

After such an obvious lack of support for my professional role and my genuine efforts to promote quality and safety in clinical trials, to have continued in my previous position would have given me cause to question my professionalism and integrity.

Reference

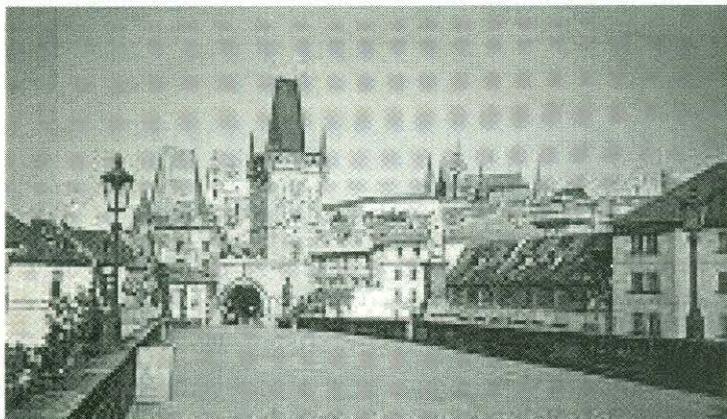
1. Bully OnLine: <http://www.successunlimited.co.uk>

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FOOD FOR THOUGHT

***Nearly all men can stand adversity, but if you
want to test a man's character, give him power***

Abraham Lincoln, U.S. president (1809-1865)



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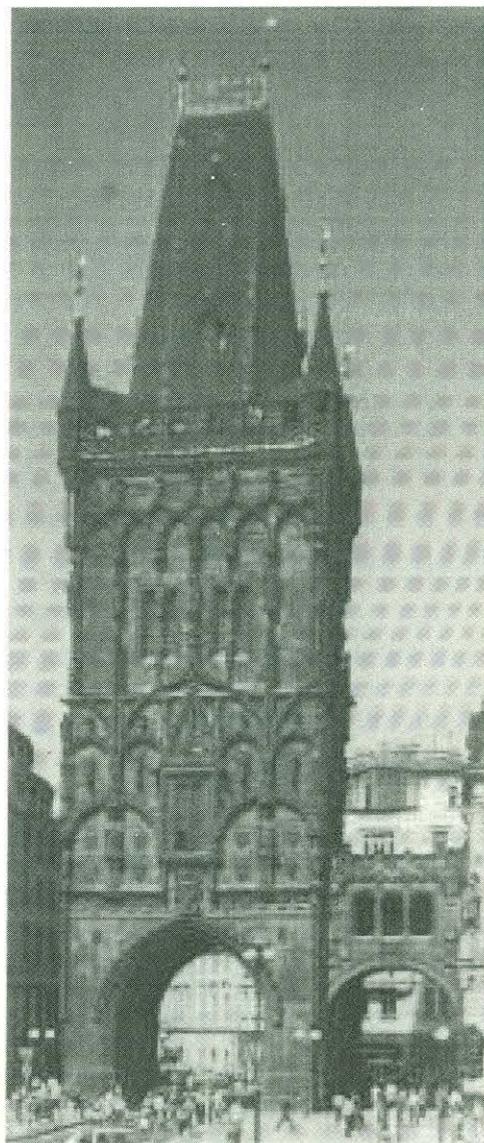
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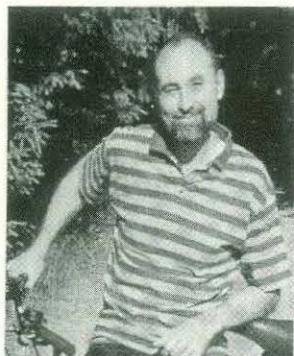
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and on the EMWA Website



Slash the Slash – or, The Art of Not Being Oblique

by Stephen de Looze

Come listen, my men, while I tell you again /The five unmistakable marks /By which you may know, wheresoever you go, /The warranted, genuine Snarks.

From "The Hunting of the Snark" by Lewis Carroll/Charles Dodgson

The snark that I will be hunting in this article is the slash, variously known as the oblique stroke, bar or mark, the slant line or the virgule. In my opinion it is the most abused punctuation mark. I am sure that other writers and editors have their own pet hates—the illiterate use of the apostrophe, wild capitalization, or a failure to distinguish between hyphens and dashes. But for me, the slash—or what I like to call "slash creep"—should be the *cause célèbre*, because medical writers seem to be as guilty of rampant abuse as anyone else. I have even challenged writers on this, who were ready to defend their "slash creep" as perfectly acceptable style.

So let us begin with the "five unmistakable marks", or the five correct uses of the "warranted, genuine Snarks". Two are exemplified at the top of this article. The first is for separating lines of poetry when written out across the page—not a common feature of medical writing! The second is for stating two equivalent, alternative names for the same thing (or person). This use does feature in our work, for example:

Paracetamol/Acetaminophen is one of the most widely prescribed NSAIDs...

The institutional review board/independent ethics committee must be informed of all serious adverse events...

The third use is as the familiar mathematical symbol for division ($y = 4x/z$), the fourth in expressions of rate or concentration (km/h, mg/ml), and the fifth in some rather specialized abbreviations and nomenclatures such as genotype designations and web addresses. In all these cases, the slash is unambiguous and, in common with its punctuation mark brethren, serves as an aid to comprehension.

When it comes to using punctuation marks other than the slash, writers do not feel impelled to imbue the mark with their own



private significance—but not so with the slash, which suffers from what may be called "the Humpty Dumpty approach". This is explained in the well-known passage from Lewis Carroll's, alias Charles Dodgson's, perhaps most famous work:

"There's glory for you!"

"I don't know what you mean by 'glory' ", Alice said.

Humpty Dumpty smiled contemptuously. "Of course you don't—till I tell you. I meant 'there's a nice knock-down argument for you!' "

"But 'glory' doesn't mean 'a nice knock-down argument' ", Alice objected.

"When I use a word", Humpty Dumpty said in a rather scornful tone, "it means just what I choose it to mean—neither more nor less".

From "Through the Looking Glass"

Below is a table, copied from an article on definitions of phases of investigation (clinical trial phases) that appeared in the American Heart Journal in April 2000. The author is none other than the famous Bob Temple, an influential American regulator at the US Food and Drug Administration, and a major contributor to the international standardization of clinical study reports and other documentation.

Table I. Contrasts between Phase II and Phase III studies

	Phase II studies	Phase III studies
Population definition	Narrow	Broad
Patient exclusion criteria	Many	Fewer
End points	Symptoms/surrogates	Symptoms/surrogates Outcomes
Size	Modest	May be (much) larger
Safety	Common events	Less common events
Duration	Short: wk/mo, extensions	Short or long; extensions possible
Dose-response studies	Good idea	Good idea
Pharmacokinetics	Formal studies	Formal studies/screen
Control	Placebo, dose/response 3-arm; add-on	Placebo; add-on Some active control
Exploratory/ confirmatory	Yes	Yes

Am Heart J 2000;139;133-135.

The slash is used no less than six times, so let us take a closer look for any of the "five, unmistakable marks".

"Symptoms/surrogates" as end points in phase II and III trials. Clearly, the two words are not alternatives for the same thing, so what is meant here exactly? From the article, it is clear that both symptoms AND surrogates can be end points in phase II trials. The slash is used to mean "and", or even just a list separator, since the two items are simply a list of two. Elsewhere in the table, the semicolon is used as the list separator (for "placebo; add-on" controls), though a comma would do the job just as well. The

Slash the Slash

matter becomes more interesting in the cell listing end points for phase III trials. Here we have the entry "Symptoms/surrogates [new line]Outcomes". Is the meaning of this cell "symptoms; surrogates; outcomes", or is something more implied by the slash that connects symptoms and surrogates but not outcomes? We don't know.

"Short: *wk/mo*, extensions" for duration of trials. The erratic punctuation in this cell makes comprehension challenging, but after some consideration we can guess that the slash here is implying a range, i.e. "in the range of weeks to months". However, that is only because we know something about clinical trials. For someone without this knowledge, or if the expression "*wk/mo*" were to occur in another context, its meaning would be far from obvious.

"*Formal studies/screen*" as a description of the pharmacokinetics. The first attempt at deciphering is "formal studies or formal screen", but with prior knowledge and a glance at the article, the slash here is doing the work of "and": pharmacokinetic investigations during phase III investigations can take the form of both formal studies and screening studies. However, without prior knowledge, we would again be left guessing.

The slash in "*Dose/response*" in the cell describing controls in phase II studies has curiously substituted for the hyphen, correctly given elsewhere in the table ("dose-response studies"). Once more, the reader is left wondering if some more subtle meaning is implied by "dose/response" than "dose-response", though by now, the sensitive reader will be beginning to realize that this table has been badly afflicted by "slash creep".

Lastly, what about that "*Exploratory/confirmatory*" in the last line? At least with regard to its primary variables, a trial cannot be both exploratory and confirmatory, so the slash here is possibly simply a substitute for "or". But if you don't know about clinical trials, this would be but one possible interpretation.



*Then the bowsprit got mixed with the rudder sometimes:
A thing, as the Bellman remarked,
That frequently happens in tropical climes,
When a vessel is, so to speak, "snarked".*

The table above is certainly well snarked. In reviewing the six uses of the slash above, we find it means, variously, "and", "or", a hyphen, a range, a list separator, and, potentially, something undefined. All six uses are different; none of them are any of the five unmistakable marks. In fact, the use of the slash to mean any of the above is by no means rare. I have found it lurking even at the heart of the EMWA Professional Development Programme, in the "Editing/Writing" option (a legacy from AMWA), which will henceforth be known as the "Editing and Writing" option. A recent brochure advertising a medical writing

conference proclaims a session to explain "what regulatory agencies really want from a report/dossier". The crucial point is that while authors think that their personal meaning for the slash is obvious, it almost always serves to obscure rather than to clarify, and may carry a quite unintended message.

As Humpty Dumpty said, "When I make a word do a lot of work like that, I always pay it extra". In fact, the slash must be paid very handsomely indeed, since it is made to do even more work than this in many documents that cross my desk. Here are some more examples.

The "and/or" problem. The expression "and/or" comes complete with its own slash and is very widely abused. This is partly out of carelessness and partly out of a failure to appreciate that the word "or" can be inclusive as well as exclusive, as illustrated by the sentence:

Confidential information can only be given to patients or their close relatives.

How many writers would not be able to resist writing "and/or" in place of "or"? However, a moment's thought shows that "and/or" would not make the sentence any clearer, and in fact it makes it harder to understand—whenever "and/or" occurs in a sentence, the reader is obliged to read it twice: once in the "and" sense, and once in the "or" sense. This can be a challenge, especially in unfamiliar material. Take this sentence from a recently issued company guideline on electronic signatures:

Electronic records must be maintained in an electronic format for the time period established by the predicate regulation and/or the sponsor's record retention procedures.

Would anyone like to guess how long records must be maintained if the regulations specify ten years and the sponsor's procedures fifteen years? In general, and/or can be replaced by "and" or by "or", rarely, by "or...as the case may be" (or some other explanation).

Organizational hierarchy. My medical writing group used to be part of the clinical research department, so we were sometimes referred to as Medical Writing/Clinical Research. This seems harmless enough, but the nomenclature is only understandable if the organization is known. I recently came across a standard operating procedure (SOP) in which a task was to be performed by the "Local Safety Officer/Medical Affairs". On first reading, I assumed that this described an organizational hierarchy, but it transpired that what was meant was "either the local safety officer, or, if no local safety officer is present, a suitably qualified person in the medical affairs department". That is an awful lot of work for a small slash to be doing! An SOP must be, above all, unambiguous if the SOP is to be effective at all; here the careless use of the slash could cause serious procedural mistakes.

Quasi-mathematical phrases. This is exemplified by the commonly used phrase "risk/benefit ratio". As we have seen, the slash is correctly used as a mathematical symbol for division, and this is carried over into much less formal expressions where no real mathematics is involved. The correct punctuation here should, of course, be a hyphen. I suspect that the phrase "dose/response" used in the table above is a further carry-over of this, even though there is no suggestion of a "ratio" here. More

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insidiously, by giving the aura of mathematical precision, the slash can be subtly misleading (or even dishonest) when used in this way.

Perhaps the most irritating use of the slash is the "*indecisiveness syndrome*", extremely common in sloppy business writing. A series of overheads recently presented at an internal meeting were all entitled "Sponsor's interpretation/position", when in fact either of the two words separated by the slash would have been adequate. The writer didn't know, or just couldn't be bothered to decide, which was preferable.

Job advertisements are a rich source of "slash creep", perhaps because they have been penned by individuals who have been exposed to "corporate-speak" for too long. Here is a small sample taken from a couple of pages from a recent edition of *New Scientist*: "...looking for a team player capable of supporting/installing/maintaining automated wet chemistry..." (would any one suffice?); "...you will have a BSc degree in electronics/physics/chemistry/mat. science..." (do you need them all?); "...based in the South Midlands/north of the M4..." (several locations?); "...applicants must have UK/EU nationality..." (is this a celebration of the fact that the UK is part of the EU, or a subtle statement of the opposite?). And repeatedly, applicants are asked to provide their "c/v".

*For although common Snarks do no manner of harm,
Yet I feel it my duty to say,
Some are Boojums—*

I once read an article on overuse of the comma, where the author described how the commas seemed to be like "tadpoles, swimming all over the page". I see those slashes like raised paving stones, causing unsuspecting readers to trip up, or at least forcing them to negotiate their way through the text with painstaking slowness. Whenever you are tempted to insert a slash (or an "and/or"), ask yourself if you are being kind to your reader, hedging your bets, or even setting a trap. The slash is almost always unnecessary, ambiguous or misleading, and leads, in the truest sense of the word, to your writing becoming oblique. My advice to everyone is: *slash the slash!* Your writing will become clearer and you will eliminate those boojums lying in wait to take you and your readers unawares.

Now **there's** glory for you!

Stephen de Looze
Head of Medical Writing, Aventis Pharma
Frankfurt, Germany

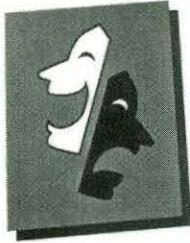


Illustrations:

P89: "He had wholly forgotten his name" from original Illustration by Henry Holiday for *The Annotated Snark* by Lewis Carroll, ed. Martin Gardner; Penguin Books 1967, 1975: 49.

P91: Humpty Dumpty from original Illustration by Sir John Tenniel for Lewis Carroll's *Alice's Adventures in Wonderland and Through the Looking Glass*; JM Dent & Sons 1954, 1970: 190.

P93: "But oh, beamish nephew, beware of the day"; from original Illustration by Henry Holiday for *The Annotated Snark* by Lewis Carroll, ed. Martin Gardner; Penguin Books 1967, 1975: 65.



The Lighter Side . . . Windows Haiku

Thanks to email circulation for these

Imagine if, instead of cryptic, geeky text strings, your computer produced error messages in Japanese haiku poetry . . .

Is the file that big?
It might be very useful.
But now it is gone.

The website you seek
Cannot be located but
Endless others exist.

Chaos reigns within.
Reflect, repent, and reboot.
Order shall return.

ABORTED effort:
Close all that you have.
You ask far too much.

First snow, then silence.
This thousand-dollar screen dies
So beautifully.

With searching comes loss
And the presence of absence:
"Protocol" not found.

The Tao that is seen
Is not the true Tao, until
You bring fresh toner.

Windows NT crashed.
I am the Blue Screen of Death.
No one hears your screams.

Stay the patient course
Of little worth is your ire
The network is down.

A crash reduces
Your expensive computer
To a simple stone.

Yesterday it worked
Today it is not working
Windows is like that.

Three things are certain:
Death, taxes, and lost data.
Guess which has occurred.

You step in the stream,
But the water has moved on.
This page is not here.

Rather than a beep
Or a rude error message,
These words: "File not found."

Having been erased,
The document you're seeking
Must now be retyped.

Serious error.
All shortcuts have disappeared.
Screen. Mind. Both are blank.

Additional submissions will be gladly accepted for a later issue.

The Changing Face of EMWA

Results from the questionnaires: 1997 – 2000
compiled by Barry Drees

*This article is the second in a series reporting the results of the great 2000 EMWA membership survey. The first article, describing what members found best and worst about EMWA as an organisation, were reported in *The Best and The Worst of EMWA*, TWS 2001; 10: 32-33.*

It has been almost 2 years since we ran one of these and EMWA has changed beyond all recognition: we now have a fully fledged and functioning educational programme, we have attained membership numbers that we could only dream of in the early days (currently about 500 members), and of course, TWS has pictures on the cover! And so, what are the members like in this new era? Well, looking at the table on the next page, one is immediately struck by what value-for-money EMWA apparently still provides; 98% of the members are satisfied with the membership fees! One usually sees numbers like that only in North Korean elections.

It would appear that very little has changed with regards to members' backgrounds and their desires from EMWA membership. Members still come mostly from backgrounds in research, the pharmaceutical industry or publishing and are looking for education, networking, information, and social contacts (although I was thrilled to see that my challenge in a previous article (TWS 2000, 9 (1): 6-7) to increase our efforts at reaching out to new members at the meetings must have borne fruit with an increase from 9% to 31%.. Good work everyone, keep it up!

Another very interesting and encouraging sign is that the percentage of non-native English speakers has markedly increased. Of course, from this little survey we cannot know whether this is due to more non-native English speakers working as medical writers in Europe, more joining EMWA, or more responding to surveys (or fewer native English speakers responding!), but whatever the reason, it certainly is an encouraging sign to see so much participation. As avid followers of TWS will know, increasing the participation of this group of members has long been a goal of mine and I'd like to think that the focus of articles and an entire issue of TWS dedicated to this theme might have helped play a role.

Another interesting trend is the percentage of responders who claim to be freelancers. This percentage has steadily increased from 16% in 1997 up to 38% last year. Again, interpreting these figures is difficult, but if taken at face value as representing EMWA membership, it suggests that a fundamental demographic change is going on in EMWA and that freelancer concerns should be much more prominent in what we do.

The percentage of freelance EMWA members has steadily increased from 16% in 1997 up to 38% last year. If taken at face value as representing EMWA membership, it suggests that a fundamental demographic change is going on in EMWA and that freelancer concerns should be much more prominent

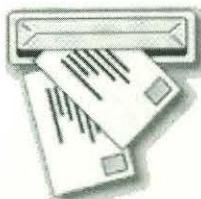
Summary of the responses for each year (where meaningful)

Category	97	99	00
Response			
Total number	41	93	75
Rate (approx.)	50%	40%	-
Satisfied with EMWA costs (answered "just right" or "what a bargain")			
Membership	84%	89%	98%
Conferences	57%	75%	82%
Workshops	87%	83%	79%
Prior background			
Research	50%	37%	51%
Pharma. industry	28%	31%	28%
Publishing	13%	7%	14%
University	13%	9%	4%
Biometrics	3%	0%	3%
First heard of EMWA			
Colleagues	54%	62%	67%
AMWA	17%	18%	6%
Literature	10%	4%	3%
Other	19%	16%	25%
English non-native speaker		19%	31%

Category	97	99	00
Membership			
Duration	2.9 yr	3.0 yr	3.1 yr
New member	29%	25%	29%
EMWA provides (multiple answers possible, % of all responses)			
Education	26%	30%	29%
Networking	26%	24%	26%
Information	25%	30%	29%
Social contacts	16%	9%	31%
Freelance work	7%	7%	6%
Other	0%	3%	1%
Previous meeting attendance			
Average (no.)	2.2	2.1	2.3
First meeting that year	23%	33%	51%
EMWA website			
Visited	61%	70%	94%
No access	15%	17%	0%
Unaware	22%	13%	3%
Job status			
Industry	84%	63%	54%
Freelance	16%	27%	38%
Consulting	0	8%	2%
Academic	0	2%	5%

The fact that the number of EMWA members to have visited our website is now close to 100% is good evidence that the internet truly has arrived in Europe (it was only 61% in 1997) and access among well-educated medical writers is now practically universal. Another interesting item is the very low number of members who heard about EMWA through AMWA, considerably decreased from previous surveys (from 18% to 6%) suggesting that independence has unfortunately brought a severing of communication as well. Perhaps the EC should consider some way of opening up cooperation with our colleagues across the pond (although it might just mean that EMWA has already poached all the European AMWA members that were interested in joining).

Finally, one last big change was in the number of members attending their first meeting that year. This probably doesn't mean that much, the explosive growth of EMWA over the last two years is probably the reason for this increase, but it goes a long way towards explaining all those fresh new faces we old-timers have been seeing at the meetings lately. Of the 75 responders to the survey, only 4 (5%) had never been to a meeting. I'm not sure that this reflects the real percentage of truly silent members, but it did provide at least a small way for these members to communicate their concerns. Any of you out there who read this are very welcome to write to TWS and express your views on anything relating to EMWA. Remember, EMWA is an organisation of the members for the members and for it to serve you better, you must speak out about what you want.



Vital Signs: Correspondence from our readers

Dear TWS

My immediate reaction to the very interesting (and well written, of course) article by Tim Albert in TWS 2001; 10 (3): 59-61 entitled, "End of Medical Journals: things are changing fast, but could it be for the better?" was one of horror. It would appear that in order for scientific publishers to survive, they need to publish electronically. The need for these publishers and their journals was also questioned - scientists could disseminate their work on their personal websites without peer review (that could come afterwards).

I would agree that publishing electronically is a thing of the future but removing peer review prior to publication is totally unacceptable to me. It is naïve to assume that ones' colleagues will read the preliminary publication on the Internet and then have the time to comprehensively review it - peer review takes time. No comment would not necessarily mean it is superb science. On the other hand, yes, it might provoke healthy electronic discussions between interested parties, but who would really want to work through all the comments/replies? - who would summarise them, I wonder? - who would have time? On the basis of my experience as a "peer reviewer", the standard of submissions varies considerably and most are/were nowhere near being acceptable for publication. Invariably, far better papers came back after the authors had taken note of the reviewers' comments (there is always more than one) but alas, many manuscripts were beyond redemption. The thought of inaccurate, incomplete and repetitive papers freely worming their way through the internet is horrendous - and there is no guarantee that they would be superbly written either!!

It was suggested that electronic publishing would lead to more papers being published because it is quicker and cheaper, but please note, "no space in the journal" is not the usual reason for rejecting papers. Tim did use the phrase, "provided they meet the scientific criteria", but then went on to extol the virtues of journals abandoning peer review?

It is naïve to assume that ones' colleagues will read the preliminary publication on the Internet and then have the time to comprehensively review it

"One of the great advantages of all this is that it could destroy the validity of publication as a performance indicator," says Tim who then implied that if peer review was abandoned and the role of technical editors extended, more people could get their work published in the more prestigious journals.

"Free from the need to validate science, journals could revert to their original role of communicating advances" - presumably therefore the technical editor position as proposed by Tim would not be interested in the value of the science? He goes on to quote Smith and Delamothe, "If journals cannot add value then they will die, which is

right and proper. But if reading them can be a pleasure not a chore then they can survive" – I would add, "rapid communication of medical advances without first checking validity could well lead to death".

Sincerely,

Linda Mizen – happy to remain naïve in the assumption that most data reported in scientific journals have been adequately reviewed.

Tim Albert responds:

I am delighted that my article prompted Linda Mizen to write such an eloquent letter. But we still disagree over one fundamental thing. I don't think there is any evidence that peer review brings us good science; in fact the message from many papers at the recent Barcelona congress on peer review was that it is not only horrendously biased, but that it gives science writing a respectability that it doesn't always deserve. Putting articles on the Web first, and then allowing comment afterwards, would make everything transparent, to the benefit of all.

Tim Albert

SATISFIED CUSTOMER

Mick Jagger should have tried it . . .

"You won't believe it, but I got a call today. Someone had read my article in TWS and is looking for a translator from English into German. Isn't that great!"

TWS contributor Anne Bartz

Meetings of Interest

The following list is presented as a service to EMWA members and is not meant to be complete. EMWA does not endorse these meetings in any way. Those having the [EMWA] symbol include presentations from EMWA members. All meetings are conducted in the English language unless otherwise indicated. If you would like to have something listed here to share with other members, please contact Barry Drees (details on back cover).

Date	Meeting/Sponsor	Location
Jan 29-30 2002	Medical Statistics for Non-statisticians Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436 Internet: www.rostrumtraining.co.uk	London, UK
Feb 4-8	Working through Drug Development Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 Internet: www.management-forum.co.uk	London, UK
Feb 7	CRF Design Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436 Internet: www.rostrumtraining.co.uk	London, UK
Feb 11-13 [EMWA]	Successful Medical Writing Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 Internet: www.management-forum.co.uk	London, UK
Feb 14-15 [EMWA]	Medical Writing Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436 Internet: www.rostrumtraining.co.uk	London, UK
Feb 26-27	Negotiation Skills Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436 Internet: www.rostrumtraining.co.uk	London, UK
Feb 26-27	Variations 2002: New Regulatory Review Requirements IIR Conferences 29 Bressenden Place, London, SW1E 5DR, UK Tel: (+44) 027 915 5055; Fax: (+44) 027 915 5001 Internet: www.iir-conferences.com/variations	London, UK
Mar 5-7	Effective Pharmaceutical Project Management Rostrum Personal Development Mildmay House, St Edwards Court, London Rd, Romford, Essex, RM7 9QD, UK Tel: (+44) 1189 697 879; Fax: (+44) 1189 335 436	London, UK

Coming Next Issue . . . (Vol. 11, No. 1, 2002)

Teamwork

Medical Writers as Quality Control

Adam Jacobs

Yes, we all know we do it, but do we ever get any credit for it? The long-awaited return of the "man in the white hat" tells us why "medical writers are uniquely well placed to help ensure that the final study report is as close to perfect as possible". Find out why medical writers are often known as the last line of defence against the cock-up and perhaps slip a copy to your manager come raise time!

The Medical Writer and the Clinical Development Team

Graham Diggory

Teamwork and interpersonal skills seem to be the medical writing buzzwords of the day, but how a medical writer actually works in a team can sometimes seem more like magic than science. Here we present the view from the front lines for writers both in industry and in CROs so you can find out how it is done without having to go to Hogwarts.

Shocking Exposé or Lesson in Ethics?

Karen Shashok

This issue's stroll into the bookstores gives us something really different, a review of the book, *The Constant Gardener* by John le Carré. Known for his best-selling spy thrillers, this time out le Carré writes about the goings-on at a global pharmaceutical firm, and it doesn't take much imagination to guess what that means. In his concluding Author's Note, le Carré states, "As my journey through the pharmaceutical jungle progressed, I came to realise that, by comparison with the reality, my story was as tame as a holiday postcard". Sure, a holiday postcard from Hades.

The Last Word

"It is said an Eastern monarch once charged his wise men to invent him a sentence to be ever in view, and which should be true and appropriate in all times and situations. They presented him the words: "And this, too, shall pass away." How much it expresses! How chastening in the hour of pride! How consoling in the depths of affliction!"

Abraham Lincoln, 16th U.S. President (1809-1865)

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